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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,949	12/09/2003	Sydney M. Finegold	111828-00113	8848

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
01/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,949	FINEGOLD, SYDNEY M.	
	Examiner	Art Unit	
	DEBBIE K. WARE	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 10-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

S.N, 10/729,949

ART UNIT 1651

DETAILED ACTION

Claims 1-3 and 10-17 are presented for consideration on the merits.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 23, 2008, has been entered.

Response to Amendment

The amendment filed October 23, 2008, has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-13 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Borody (5,443,826), see enclosed PTO-892 Form .

Claims are drawn to a method of treating disease associated with an abnormal gastrointestinal flora (i.e. Clostridium capable of producing a toxin) selected from juvenile rheumatoid arthritis comprising administering to a patient suffering therefrom an antibacterial agent (including an antibiotic, i.e. metronidazole, or vancomycin, etc., or bacteriophage or radionuclide). The antimicrobial composition is in the form of a tablet or capsule which is enteric coated.

Borody teaches a method of treating disease associated with an abnormal gastrointestinal flora (i.e. Clostridum capable of producing a toxin) wherein the disease is rheumatoid arthritis or autoimmune disease. Note abstract and col. 2, line 46, and col. 7, line 35. The method includes administering to a patient suffering therefrom an antibacterial agent (i.e. Vancomycin or metronidiazole, see col. 5, lines 55-60 and col. 6, line 59); and then probiotic was administered, note col. 6, lines 45-65 and note col. 7, lines 30-40. Further, administering the composition in the form of enteric-coated capsules is disclosed, see col. 5, line 1. Several desirable bacteria are disclosed in Table 1, note Bacterioides, at col. 6, line 21.

Borody further teaches the abnormal microorganism is a bacterium. Also the antibacterial agent can be an antibiotic and a probiotic such as Bacterioides is disclosed to be administered in addition to an antibacterial agent. The Clostridium bacterium is disclosed to produce a toxic metabolite. Further, the antimicrobial composition is in the form of an enteric coated tablet or capsule. Also the abnormal microbe is Clostridium. The administering step includes both administering an antibiotic and probiotic for treating a disease associated with an abnormal gut flora, and the disease is selected from an autoimmune disease or rheumatoid arthritis of which can occur in young people.

The claims are identical to the teachings of Borody and are, therefore, considered to be anticiapted by the teachings therein. However, in the alternative that there is some unidentified claim characteristic for which is not disclosed then the difference is considered to be so slight as to render the claims prima facie obvious. One of skill in the art would have been motivated to administer both an antibacterial agent, such as an antibiotic, like Vancomycin, and then to administer a Bacteriodes probiotic or some other one to treat an autoimmune disease like IBS or some other autoimmune disease, and to also treat arthritis.

Borody clearly teach that these diseases are treatable by administering both an antibacterial agent and probiotic, and also teaches administering both an antibiotic and subsequently a probiotic. In each treatment of the exemplifed cited disclosure Borody administers an antibiotic and then subsequently administers a probiotic to treat the suffering patient in need thereof.

In the alternative, to administer both the antibacterial agent and then a probiotic agent is clearly taught or is at least obvious over the cited Borody reference. Thus, in the alternative the claims are at least rendered obvious over the cited reference. However, the Examiner believes that the claims are explicitly taught by the cited reference but in the alternative that there is a difference then it is deemed to be so slight as to render, at the time the claimed invention was made, the claims obvious over the cited prior art because one of skill would have been motivated to administer both the antibacterial agent and the probiotic agent with an expectation of successful results.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Borody, cited and discussed above in view of newly cited Farmer et al (US 7374753) and newly cited Armel abstract.

Claims are further drawn to a method as discussed above wherein the antibacterial agent is a radionuclide active against spores of the abnormal microbe or a bacteriophage specific for the abnormal microbe.

Borody is discussed above, and further teaches the abnormal microorganism is a bacterium. Also the antibacterial agent can be an antibiotic and a probiotic such as Bacterioides is disclosed to be administered in addition to an antibacterial agent. The

Clostridium bacterium is disclosed to produce a toxic metabolite. Further, the antimicrobial composition is in the form of an enteric coated tablet or capsule. Also the abnormal microbe is Clostridium. The administering step includes both administering an antibiotic and probiotic for treating a disease associated with an abnormal gut flora, and the disease is selected from an autoimmune disease or rheumatoid arthritis of which can occur in young people.

The claims differ from Borody in that a radionuclide or bacteriophage is not disclosed.

Farmer et al teach bateriophage are antibacterial because they inhibit the growth of specific bacteria, note col. 1, lines 20-25.

Armel teach control of spore-forming bacteria with radionuclides, see entire abstract only.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include as the antibacterial agents of Borody's disease treatment method those disclosed as having antibacterial activity by Farmer et al and the Armel abstract for a method of treating disease assoicated with an abnormal gastric flora selected from an autoimmune disease and/or arthritis.

Clearly to select as an antibacterial agent a radionuclide or bacteriophage for use in the method of Borody is an obvious choice amongst functional equivalents well recongized in the cited prior art. One of skill would have been motivated to select a bacteriophage or radionuclide with the expectation of successful results because they are well known for their antibacterial activity.

Also one of skill in the art would have been capable of determining the optimal antibacterial agent to select dependent upon the pathogenic effect desired because they are well known and taught in the cited prior art to be effective for treating pathogenic bacteria. Therefore, in the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art.

Response to Arguments

Applicant's arguments filed October 23, 2008, have been fully considered but they are not persuasive. The argument that the current claims "consist of" two steps is noted, however, the treating with an antibacterial agent (aka: antibiotic) will inherently remove existing enteric flora. Hence, a reading of Borody can effectively read on two steps and meet the new limitation of "consist of" language. The arugment that the presently claimed invention does not remove the existing enteric flora, is noted, however, the claims do not recite this and hence the step of providing the antibacterial agent removes the existing enteric flora. The present claims do not recite that only the abnormal microbe is removed, it merely selectively treats for this microbe and the reference also selectively treats and which is dependent upon the antibiotic. Thus, Borody does indeed anticipate the presently claimed invention.

With regard to obviousness, as noted above and for these reasons Applicants do not omit removal of enteric flora while treating with an antibacterial agent. These agents do remove enteric flora. Note the "consisting of" language encompasses the steps employed by the method and not the efficacy of the antimicrobial composition. The claims read on administering an antibacterial agent and then administering a

probiotic agent wherein the antibacterial agent is effective against the abnormal microorganism. However, in now way is the efficacy of the antibacterial agent limited in the claim because no such limitation is described for the agent in the claims. Thus, the claims remain rejected for these reasons and those of record.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the previously enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the previously enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBBIE K. WARE whose telephone number is (571)272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah K. Ware/
Deborah K. Ware
Examiner
Art Unit 1651